

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

TENAX THERAPEUTICS, INC.

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED March 31, 2020

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 001-34600

TENAX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

26-2593535
(I.R.S. Employer Identification No.)

ONE Copley Parkway, Suite 490, Morrisville, North Carolina 27560
(Address of principal executive offices)

(919) 855-2100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	TENX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-Accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes No

As of May 11, 2020, the registrant had outstanding 9,218,556 shares of Common Stock.

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PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 4,358,679	\$ 4,905,993
Marketable securities	498,535	493,884
Prepaid expenses	941,144	780,952
Total current assets	<u>5,798,358</u>	<u>6,180,829</u>
Right of use asset	142,607	169,448
Property and equipment, net	5,446	6,559
Other assets	8,435	8,435
Total assets	<u>\$ 5,954,846</u>	<u>\$ 6,365,271</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,805,926	\$ 1,661,054
Accrued liabilities	699,525	871,341
Total current liabilities	<u>2,505,451</u>	<u>2,532,395</u>
Lease liability	30,743	60,379
Total liabilities	<u>2,536,194</u>	<u>2,592,774</u>
Commitments and contingencies; see Note 6		
Stockholders' equity		
Preferred stock, undesignated, authorized 9,999,790 shares; See Note 7		
Series A Preferred stock, par value \$.0001, issued and outstanding 210 and 38,606, respectively	-	4
Common stock, par value \$.0001 per share; authorized 400,000,000 shares; issued and outstanding 8,008,243 and 6,741,860, respectively	801	674
Additional paid-in capital	242,242,095	239,939,797
Accumulated other comprehensive (loss) gain	(1,164)	458
Accumulated deficit	<u>(238,823,080)</u>	<u>(236,168,436)</u>
Total stockholders' equity	<u>3,418,652</u>	<u>3,772,497</u>
Total liabilities and stockholders' equity	<u>\$ 5,954,846</u>	<u>\$ 6,365,271</u>

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Three months ended March 31,	
	2020	2019
	(Unaudited)	(Unaudited)
Operating expenses		
General and administrative	\$ 1,322,959	\$ 1,179,009
Research and development	1,342,526	482,767
Total operating expenses	<u>2,665,485</u>	<u>1,661,776</u>
Net operating loss	2,665,485	1,661,776
Other income, net	(10,841)	(44,331)
Net loss	<u>\$ 2,654,644</u>	<u>\$ 1,617,445</u>
Unrealized loss (gain) on marketable securities	1,622	(1,289)
Total comprehensive loss	<u>\$ 2,656,266</u>	<u>\$ 1,616,156</u>
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.33)
Weighted average number of common shares outstanding, basic and diluted	6,974,387	4,887,075

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated other comprehensive gain (loss)	Accumulated deficit	Total stockholders' equity
	Number of Shares	Amount	Number of Shares	Amount				
Balance at December 31, 2018	2,854,593	\$ 285	3,792,249	\$ 379	\$ 239,572,094	\$ 516	\$(227,801,743)	\$ 11,771,531
Compensation on options and restricted stock issued			12,195	1	60,294			60,295
Common stock issued for convertible preferred stock	(2,299,990)	(230)	2,299,990	230				-
Exercise of warrants			50,000	5	96,495			96,500
Adoption of ASC Topic 842:								
Leases							27,670	27,670
Unrealized gain on marketable securities						1,289		1,289
Net loss							(1,617,445)	(1,617,445)
Balance at March 31, 2019	554,603	\$ 55	6,154,434	\$ 615	\$ 239,728,883	\$ 1,805	\$(229,391,518)	\$ 10,339,840
Balance at December 31, 2019	38,606	\$ 4	6,741,860	\$ 674	\$ 239,939,797	\$ 458	\$(236,168,436)	\$ 3,772,497
Common stock and pre-funded warrants sold, net of offering costs			750,000	75	2,129,930			2,130,005
Compensation on options issued					72,376			72,376
Common stock issued for services rendered			77,987	8	99,992			100,000
Common stock issued for convertible preferred stock	(38,396)	(4)	38,396	4				-
Exercise of warrants			400,000	40	-			40
Unrealized loss on marketable securities						(1,622)		(1,622)
Net loss							(2,654,644)	(2,654,644)
Balance at March 31, 2020	210	\$ -	8,008,243	\$ 801	\$ 242,242,095	\$ (1,164)	\$(238,823,080)	\$ 3,418,652

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months ended March 31,	
	2020	2019
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (2,654,644)	\$ (1,617,445)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,113	1,114
Amortization of right of use asset	26,841	24,823
Loss on disposal of property and equipment	-	522
Issuance and vesting of compensatory stock options and warrants	72,376	60,295
Issuance of common stock for services rendered	25,000	-
Amortization of premium on marketable securities	58	(475)
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	(85,192)	91,157
Accounts payable and accrued liabilities	(26,945)	(668,915)
Long term portion of lease liability	(29,636)	(23,887)
Net cash used in operating activities	<u>(2,671,029)</u>	<u>(2,132,811)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable securities	(146,298)	(70,231)
Sale of marketable securities	139,968	65,000
Purchase of property and equipment	-	(3,574)
Net cash used in investing activities	<u>(6,330)</u>	<u>(8,805)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds for issuance of common stock and pre-funded warrants, net of issuance costs	2,130,005	-
Proceeds from the exercise of warrants	40	96,500
Net cash provided by financing activities	<u>2,130,045</u>	<u>96,500</u>
Net change in cash and cash equivalents	<u>(547,314)</u>	<u>(2,045,116)</u>
Cash and cash equivalents, beginning of period	<u>4,905,993</u>	<u>12,367,321</u>
Cash and cash equivalents, end of period	<u>\$ 4,358,679</u>	<u>\$ 10,322,205</u>

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

TENAX THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

NOTE 1. DESCRIPTION OF BUSINESS

Tenax Therapeutics, Inc. (the “Company”) was originally formed as a New Jersey corporation in 1967 under the name Rudmer, David & Associates, Inc., and subsequently changed its name to Synthetic Blood International, Inc. On June 17, 2008, the stockholders of Synthetic Blood International approved the Agreement and Plan of Merger dated April 28, 2008, between Synthetic Blood International and Oxygen Biotherapeutics, Inc., a Delaware corporation. Oxygen Biotherapeutics was formed on April 17, 2008 by Synthetic Blood International to participate in the merger for the purpose of changing the state of domicile of Synthetic Blood International from New Jersey to Delaware. Certificates of Merger were filed with the states of New Jersey and Delaware and the merger was effective June 30, 2008. Under the Plan of Merger, Oxygen Biotherapeutics was the surviving corporation and each share of Synthetic Blood International common stock outstanding on June 30, 2008 was converted to one share of Oxygen Biotherapeutics common stock. On September 19, 2014, the Company changed its name to Tenax Therapeutics, Inc.

On October 18, 2013, the Company created a wholly owned subsidiary, Life Newco, Inc., a Delaware corporation (“Life Newco”), to acquire certain assets of Phyxius Pharma, Inc., a Delaware corporation (“Phyxius”) pursuant to an Asset Purchase Agreement, dated October 21, 2013 (the “Asset Purchase Agreement”), by and among the Company, Life Newco, Phyxius and the stockholders of Phyxius (the “Phyxius Stockholders”). As further discussed in Note 5 below, on November 13, 2013, under the terms and subject to the conditions of the Asset Purchase Agreement, Life Newco acquired certain assets, including a license granting Life Newco an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United States and Canada.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include all adjustments (consisting of normal and recurring adjustments) necessary for a fair presentation of these financial statements. The condensed consolidated balance sheet on December 31, 2019 has been derived from the Company’s audited consolidated financial statements included in its Annual Report on Form 10-K for the period ended December 31, 2019. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) have been condensed or omitted pursuant to Article 8 of Regulation S-X of the Securities and Exchange Commission (“SEC”) rules and regulations. Operating results for the three-month period ended March 31, 2020 are not necessarily indicative of results for the full year or any other future periods. As such, it is suggested that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019.

Going Concern

Management believes the accompanying condensed consolidated financial statements have been prepared in conformity with GAAP, which contemplate continuation of the Company as a going concern. The Company has an accumulated deficit of \$238,823,080 on March 31, 2020 and \$236,168,436 on December 31, 2019 and used cash in operations of \$2,671,029 and \$2,132,811 during the three months ended March 31, 2020 and 2019, respectively. The Company requires substantial additional funds to complete clinical trials and pursue regulatory approvals. Management is actively seeking additional sources of equity and/or debt financing; however, there is no assurance that any additional funding will be available.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the accompanying March 31, 2020 balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company’s ability to meet its financing requirements on a continuing basis, to maintain present financing, and to generate cash from future operations. These factors, among others, raise substantial doubt about the Company’s ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Use of Estimates

In preparing the unaudited condensed consolidated financial statements, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the dates of the unaudited condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from these estimates and the operating results for the interim periods presented are not necessarily indicative of the results expected for the full year.

On an ongoing basis, management reviews its estimates to ensure that these estimates appropriately reflect changes in the Company’s business and new information as it becomes available. If historical experience and other factors used by management to make these estimates do not reasonably reflect future activity, the Company’s results of operations and financial position could be materially impacted.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts and transactions of the Company and Life Newco. All material intercompany transactions and balances have been eliminated in consolidation.

Liquidity and Management's Plan

On March 31, 2020, the Company had cash and cash equivalents, including the fair value of its marketable securities, of approximately \$4.9 million. The Company used \$2.7 million of cash for operating activities during the three months ended March 31, 2020 and had stockholders' equity of \$3.4 million, versus \$3.8 million on December 31, 2019.

The Company expects to continue to incur expenses related to development of levosimendan for pulmonary hypertension and other potential indications, as well as identifying and developing other potential product candidates. Based on its resources at March 31, 2020, the Company believes that it has sufficient capital to fund its planned operations through the third quarter of calendar year 2020. However, the Company will need substantial additional financing in order to fund its operations beyond such period and thereafter until it can achieve profitability, if ever. The Company depends on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its product candidates to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

The continued spread of COVID-19 globally could adversely affect the Company's ability to retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some of these investigators and site staff may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede movement or interrupt healthcare services, or if they become infected with COVID-19 themselves, which would delay the Company's ability to complete its phase 2 clinical trial or release clinical trial results.

To the extent that the Company raises additional funds by issuing shares of its common stock or other securities convertible or exchangeable for shares of common stock, stockholders will experience dilution, which may be significant. In the event the Company raises additional capital through debt financings, the Company may incur significant interest expense and become subject to covenants in the related transaction documentation that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates or grant licenses on terms that may not be favorable to the Company.

Any or all of the foregoing may have a material adverse effect on the Company's business and financial performance.

Net Loss per Share

Basic net loss per share, which excludes antidilutive securities, is computed by dividing net loss by the weighted-average number of common shares outstanding for that particular period. In contrast, diluted net loss per share considers the potential dilution that could occur from other equity instruments that would increase the total number of outstanding shares of common stock. Such amounts include shares potentially issuable under outstanding options, restricted stock and warrants.

The following outstanding options, warrants and restricted stock were excluded from the computation of basic and diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect.

	Three months ended March 31,	
	2020	2019
Warrants to purchase common stock	14,362,007	10,640,718
Options to purchase common stock	581,694	241,735
Convertible preferred shares outstanding	210	554,603

Leases

The Company determines if an arrangement includes a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities, and long-term lease liabilities in the Company's condensed consolidated balance sheets. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses the incremental borrowing rate based on the information available at the lease commencement date. The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. The Company's leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that the Company will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected to account for leases with an initial term of 12 months or less similar to previous guidance for operating leases, under which the Company will recognize those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued an accounting standard intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740, Income Taxes and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. The Company is currently evaluating this standard, but it does not believe the adoption of the new guidance will have a material impact on its consolidated financial statements.

In June 2016, the FASB issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard requires that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2023, with early adoption permitted. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. The Company does not believe the adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

NOTE 3. FAIR VALUE

The Company determines the fair value of its financial assets and liabilities in accordance with the Accounting Standards Codification ("ASC") 820 Fair Value Measurements. The Company's balance sheet includes the following financial instruments: cash and cash equivalents, investments in marketable securities, and warrant liabilities. The Company considers the carrying amount of its cash and cash equivalents to approximate fair value due to the short-term nature of these instruments.

Accounting for fair value measurements involves a single definition of fair value, along with a conceptual framework to measure fair value, with a fair value defined as "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date." The fair value measurement hierarchy consists of three levels:

Level one	Quoted market prices in active markets for identical assets or liabilities;
Level two	Inputs other than level one inputs that are either directly or indirectly observable; and
Level three	Unobservable inputs developed using estimates and assumptions, which are developed by the reporting entity and reflect those assumptions that a market participant would use.

The Company applies valuation techniques that (1) place greater reliance on observable inputs and less reliance on unobservable inputs and (2) are consistent with the market approach, the income approach and/or the cost approach, and include enhanced disclosures of fair value measurements in the Company's condensed consolidated financial statements.

Investments in Marketable Securities

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive income/(loss), unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in other income in the condensed consolidated statements of comprehensive loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. As of March 31, 2020, the Company believes that the costs of its investments are recoverable in all material respects.

The following table summarizes the fair value of the Company's investments by type. The estimated fair value of the Company's fixed income investments is classified as Level 2 in the fair value hierarchy as defined in GAAP. These fair values are obtained from independent pricing services which utilize Level 2 inputs:

	March 31, 2020				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized losses	Estimated Fair Value
Corporate debt securities	\$ 496,101	\$ 3,596	\$ 424	\$ (1,586)	\$ 498,535
Total investments	<u>\$ 496,101</u>	<u>\$ 3,596</u>	<u>\$ 424</u>	<u>\$ (1,586)</u>	<u>\$ 498,535</u>

All of the Company's investments have scheduled maturities of less than one year as of March 31, 2020 and December 31, 2019.

The following tables summarize information regarding assets and liabilities measured at fair value on a recurring basis as of March 31, 2020 and December 31, 2019:

	Balance as of March 31, 2020	Fair Value Measurements at Reporting Date Using		
		Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Current Assets				
Cash and cash equivalents	\$ 4,358,679	\$ 4,358,679	\$ -	\$ -
Marketable securities	\$ 498,535	\$ -	\$ 498,535	\$ -

	Balance as of December 31, 2019	Fair Value Measurements at Reporting Date Using		
		Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Current Assets				
Cash and cash equivalents	\$ 4,905,993	\$ 4,905,993	\$ -	\$ -
Marketable securities	\$ 493,884	\$ -	\$ 493,884	\$ -

There were no significant transfers between levels in the three months ended March 31, 2020.

NOTE 4. BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment consist of the following as of March 31, 2020 and December 31, 2019:

	March 31, 2020	December 31, 2019
Office furniture and fixtures	\$ 57,951	\$ 130,192
Computer equipment and software	22,280	80,669
	80,231	210,861
Less: Accumulated depreciation	(74,785)	(204,302)
	<u>\$ 5,446</u>	<u>\$ 6,559</u>

Depreciation expense was approximately \$1,100 for each of the three months ended March 31, 2020 and 2019.

Accrued liabilities

Accrued liabilities consist of the following as of March 31, 2020 and December 31, 2019:

	March 31, 2020	December 31, 2019
Operating costs	\$ 503,023	\$ 426,115
Lease liability	114,350	111,353
Employee related	82,152	333,873
	<u>\$ 699,525</u>	<u>\$ 871,341</u>

NOTE 5. LEASE

In January 2011, the Company entered into the Lease with Concourse Associates, LLC for office facilities located at the premises in Morrisville, North Carolina (the "Lease"). The Lease was amended in August 2015 to extend the term for the 5,954 square foot rental. The current term began on March 1, 2016 and continues for 64 months to September 30, 2021. Rent payments began on July 1, 2016, following the conclusion of a four-month rent abatement period. The Company has two five-year options to extend the Lease and a one-time option to terminate the Lease thirty-six months after the commencement of the initial term if no additional space ("Expansion Space") became available; none of these optional periods have been considered in the determination of the right-of-use asset or the lease liability for the Lease as the Company did not consider it reasonably certain that it would exercise any such options. The Lease further provides that the Company is obligated to pay to landlord certain variable costs, including taxes and operating expenses. The Company also has a right of first offer to lease the Expansion Space, of no less than 1,000 square feet, as that additional space becomes available adjacent to the premises over the remainder of the initial term of the Lease, at the same rate per square foot as the current premises, with an extension of the term of sixty additional months starting at the commencement date of acquiring the Expansion Space.

The Company performed an evaluation of its other contracts with customers and suppliers in accordance with ASC 842 and determined that, except for the Lease described above, none of the Company's contracts contain a lease.

The balance sheet classification of our lease liabilities was as follows:

	March 31, 2020	December 31, 2019
Current portion included in accrued liabilities	\$ 114,350	\$ 111,353
Long term lease liability	30,743	60,379
	<u>\$ 145,093</u>	<u>\$ 171,732</u>

As of March 31, 2020, the maturities of our operating lease liabilities were as follows:

Year ending December 31,

2020	\$ 91,185
2021	61,803
Total lease payments	<u>\$ 152,988</u>
Less: Imputed interest	<u>(7,895)</u>
Operating lease liability	<u><u>\$ 145,093</u></u>

Operating lease liabilities are based on the net present value of the remaining Lease payments over the remaining Lease term. In determining the present value of lease payments, the Company used the incremental borrowing rate based on the information available at the Lease commencement date. As of March 31, 2020, the remaining Lease term is 1.25 years and the discount rate used to determine the operating lease liability was 8.0%. For the three months ending March 31, 2020, the Company paid \$30,550 in total lease expenses, including \$651 for common area maintenance charges.

NOTE 6. COMMITMENTS AND CONTINGENCIES

Simdax license agreement

On November 13, 2013, the Company acquired, through its wholly owned subsidiary, Life Newco, that certain License Agreement (the “License”), dated September 20, 2013 by and between Phyxius and Orion Corporation, a global healthcare company incorporated under the laws of Finland (“Orion”), and that certain Side Letter, dated October 15, 2013 by and between Phyxius and Orion. The License grants the Company an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan (the “Product”) in the United States and Canada (the “Territory”) from Orion. Pursuant to the License, the Company must use Orion’s “Simdax®” trademark to commercialize the Product. The License also grants to the Company a right of first refusal to commercialize new developments of the Product, including developments as to the formulation, presentation, means of delivery, route of administration, dosage or indication, i.e. line extension products. Orion’s ongoing role under the License includes sublicense approval, serving as the sole source of manufacture, holding a first right to enforce intellectual property rights in the Territory, and certain regulatory participation rights. Additionally, the Company must grant back to Orion a broad non-exclusive license to any patents or clinical trial data related to the Product developed by the Company under the License. The License has a fifteen (15) year term, provided, however, that the License will continue after the end of the fifteen-year term in each country in the Territory until the expiration of Orion’s patent rights in the Product in such country.

Pursuant to the terms of the License, the Company paid to Orion a non-refundable up-front payment in the amount of \$1.0 million. The License also includes the following development milestones for which the Company shall make non-refundable payments to Orion no later than twenty-eight (28) days after the occurrence of the applicable milestone event: (i) \$2.0 million upon the grant of FDA approval, including all registrations, licenses, authorizations and necessary approvals, to develop and/or commercialize the Product in the United States; and (ii) \$1.0 million upon the grant of regulatory approval for the Product in Canada. Once commercialized, the Company is obligated to make certain non-refundable commercialization milestone payments to Orion, aggregating up to \$13.0 million, contingent upon achievement of certain cumulative net sales amounts in the Territory. The Company must also pay Orion tiered royalties based on net sales of the Product in the Territory made by the Company and its sublicensees. After the end of the term of the License, the Company must pay Orion a royalty based on net sales of the Product in the Territory for as long as the Company sells the Product in the Territory.

As of March 31, 2020, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

In June 2019, Orion filed a request for arbitration against the Company seeking a declaration regarding the correct interpretation of the line extension provisions of the License and whether or not such provisions apply to the oral form of levosimendan recently developed by Orion. Additionally, Orion requested the Company reimburse Orion for all legal fees associated with the arbitration. The Company submitted its response to the request for arbitration and rejected Orion’s position that the oral formation was not a line extension product under the License and requested Orion reimburse the Company for all legal fees associated with the arbitration. The hearing on this matter was held before the arbitral tribunal on April 7 and April 8, 2020. The Final Award is to be rendered on or before May 31, 2020.

NOTE 7. STOCKHOLDERS’ EQUITY

Preferred Stock

Under the Company’s Certificate of Incorporation, the Board of Directors is authorized, without further stockholder action, to provide for the issuance of up to 10,000,000 shares of preferred stock, par value \$0.0001 per share, in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations and restrictions thereof.

Series A Stock

On December 11, 2018, the Company closed its underwritten offering of 5,181,346 units for net proceeds of approximately \$9 million. Each unit consists of (a) one share of the Company’s Series A convertible preferred stock, par value \$0.0001 per share (the “Series A Stock”), (b) a two-year warrant to purchase one share of common stock at an exercise price of \$1.93 (the “Series 1 Warrants”), and (c) a five-year warrant to purchase one share of common stock at an exercise price of \$1.93 (the “Series 2 Warrants”). In accordance with ASC 480, the estimated fair value of \$1,800,016 for the beneficial conversion feature was recognized as a deemed dividend on the Series A Stock during the year ended December 31, 2019.

The table below sets forth a summary of the designation, powers, preferences and rights of the Series A Stock.

Conversion	<p>Subject to the ownership limitations described below, the Series A Stock is convertible at any time at the option of the holder into shares of the Company's common stock at a conversion ratio determined by dividing the stated value of the Series A Stock by a conversion price of \$1.93 per share. The conversion price is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.</p> <p>The Company will not affect any conversion of the Series A Stock, nor shall a holder convert its shares of Series A Stock, to the extent that such conversion would cause the holder to have acquired, through conversion of the Series A Stock or otherwise, beneficial ownership of a number shares of common stock in excess of 4.99% (or, at the election of the holder prior to the issuance of any shares of Series A Stock, 9.99%) of the common stock outstanding after giving effect to such exercise.</p>
Dividends	<p>In the event the Company pays dividends on its shares of common stock, the holders of the Series A Stock will be entitled to receive dividends on shares of Series A Stock equal, on an as-if-converted basis, to and in the same form as paid on the common stock. No other dividends will be paid on the shares of Series A Stock.</p>
Liquidation	<p>Upon any liquidation, dissolution or winding up of the Company after payment or provision for payment of debts and other liabilities of the Company, the holders of Series A Stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount equal to the amount that a holder of common stock would receive if the Series A Stock were fully converted to common stock, which amounts will be paid pari passu with all holders of common stock.</p>
Voting rights	<p>Shares of Series A Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series A Stock will be required to amend the terms of the Series A Stock or to take other action that adversely affects the rights of the holders of Series A Stock.</p>

As of December 31, 2019, there were 38,606 shares of Series A Stock outstanding. During the three months ended March 31, 2020, an additional 38,396 shares of Series A Stock were converted into 38,396 shares of common stock. As of March 31, 2020, there were 210 shares of Series A Stock outstanding.

Common Stock

The Company's Certificate of Incorporation authorizes it to issue 400,000,000 shares of \$0.0001 par value common stock. As of March 31, 2020 and December 31, 2019, there were 8,008,243 and 6,741,860 shares of common stock issued and outstanding, respectively.

On March 13, 2020, the Company completed a registered direct offering to a single healthcare-focused institutional investor for the issuance and sale of 750,000 shares of its common stock at a purchase price of \$1.1651 per share and pre-funded warrants to purchase up to 1,610,313 shares of its common stock, at a purchase price of \$1.1650 per pre-funded warrant (which represents the per share offering price for the common stock less \$0.0001, the exercise price of each pre-funded warrant), for gross proceeds of approximately \$2.75 million, priced at-the-market under Nasdaq rules. Additionally, in a concurrent private placement, the Company issued to the investor unregistered warrants to purchase up to 2,360,313 shares of its common stock. The unregistered warrants have an exercise price of \$1.04 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. The net proceeds from the offerings, after deducting placement agent fees and other direct offering expenses were approximately \$2.125 million. The fair value allocated to the common stock, warrants and pre-funded warrants was \$0.5 million, \$1.1 million and \$1.1 million, respectively. 400,000 of the pre-funded warrants were exercised during the period ended March 31, 2020.

Warrants

March 2020 Warrants

As part of the March 2020 registered direct offering, the Company issued unregistered warrants to purchase 2,360,313 shares of its common stock at an exercise price of \$1.04 per share and contractual term of five and one-half years. The unregistered warrants were offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Regulation D promulgated thereunder and, along with the shares of common stock underlying the warrants, have not been registered under the Securities Act, or applicable state securities laws. In accordance with ASC 480, these warrants are classified as equity and their relative fair value of approximately \$1.1 million was recognized as additional paid in capital during the quarter ended March 31, 2020. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

Warrants Issued for Services

In connection with the March 2020 offering described above, the Company issued designees of the placement agent warrants to purchase 177,023 shares of common stock at an exercise price of \$1.4564 and a contractual term of five years. In accordance with ASC 815, these warrants are classified as equity and its estimated fair value of \$66,201 was recognized as additional paid in capital during the quarter ended March 31, 2020. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

In connection with the March 2020 offering described above, the Company issued to its previous underwriter a warrant to purchase 94,413 shares of common stock at an exercise price of \$1.4564 per share and contractual term of five years. In accordance with ASC 815, this warrant is classified as equity and its estimated fair-value of \$35,308 was recognized as additional paid in capital during the quarter ended March 31, 2020. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

As of March 31, 2020, the Company has 14,362,007 warrants outstanding. The following table summarizes the Company's warrant activity for the three months ended March 31, 2020.

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2019	10,519,945	\$ 1.94
Issued	4,242,062	0.67
Exercised	(400,000)	0.00
Outstanding at March 31, 2020	14,362,007	\$ 1.62

2016 Stock Incentive Plan

In June 2016, the Company adopted the 2016 Stock Incentive Plan (the "2016 Plan"). Under the 2016 Plan, with the approval of the Compensation Committee of the Board of Directors, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units, cash-based awards or other stock-based awards. On June 16, 2016, the Company's stockholders approved the 2016 Plan and authorized for issuance under the 2016 Plan a total of 150,000 shares of common stock. On June 13, 2019, the Company's stockholders approved an amendment to the 2016 Plan which increased the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 750,000 shares, up from 150,000 previously authorized.

The following table summarizes the shares available for grant under the 2016 Plan for the three months ended March 31, 2020:

	Shares Available for Grant
Balances, at December 31, 2019	697,500
Options granted	(337,500)
Balances, at March 31, 2020	360,000

2016 Plan Stock Options

Stock options granted under the 2016 Plan may be either incentive stock options ("ISOs"), or nonqualified stock options ("NSOs"). ISOs may be granted only to employees. NSOs may be granted to employees, consultants and directors. Stock options under the 2016 Plan may be granted with a term of up to ten years and at prices no less than fair market value at the time of grant. Stock options granted generally vest over three to four years.

The following table summarizes the outstanding stock options under the 2016 Plan for the three months ended March 31, 2020:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances at December 31, 2019	52,500	\$ 5.89
Options granted	337,500	1.18
Balances at March 31, 2020	390,000	\$ 1.81

The Company chose the "straight-line" attribution method for allocating compensation costs of each stock option over the requisite service period using the Black-Scholes Option Pricing Model to calculate the grant date fair value.

The Company recorded compensation expense for these stock option grants of \$60,161 and \$29,731 for the three months ended March 31, 2020 and 2019, respectively.

As of March 31, 2020, there were unrecognized compensation costs of approximately \$327,133 related to non-vested stock option awards under the 2016 Plan that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.82 years.

The Company used the following assumptions to estimate the fair value of options granted under the 2016 Plan for the three months ended March 31, 2020:

	Three months ended March 31, 2020
Risk-free interest rate (weighted average)	1.03%
Expected volatility (weighted average)	97.59%
Expected term (in years)	7
Expected dividend yield	0.00%

Risk-Free Interest Rate The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of the Company's stock options.

Expected Volatility The expected stock price volatility for the Company's common stock was determined by examining the historical volatility and trading history for its common stock over a term consistent with the expected term of its options.

Expected Term The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the Company's historical experience with its stock option grants.

Expected Dividend Yield The expected dividend yield of 0% is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not anticipate paying any dividends in the near future.

Forfeitures Stock compensation expense recognized in the statements of operations for the three months ended March 31, 2020 is based on awards ultimately expected to vest, and it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on the Company's historical experience.

1999 Amended Stock Plan

In October 2000, the Company adopted the 1999 Stock Plan, as amended and restated on June 17, 2008 (the "1999 Plan"). Under the 1999 Plan, with the approval of the Compensation Committee of the Board of Directors, the Company could grant stock options, restricted stock, stock appreciation rights and new shares of common stock upon exercise of stock options. On March 13, 2014, the Company's stockholders approved an amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 200,000 shares, up from 15,000 previously authorized. On September 15, 2015, the Company's stockholders approved an additional amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 250,000 shares, up from 200,000 previously authorized. The 1999 Plan expired on June 17, 2018 and no new grants may be made under that plan after that date. However, unexpired awards granted under the 1999 Plan remain outstanding and subject to the terms of the 1999 Plan.

1999 Plan Stock Options

Stock options granted under the 1999 Plan may be either ISOs or NSOs. ISOs could be granted only to employees. NSOs could be granted to employees, consultants and directors. Stock options under the 1999 Plan could be granted with a term of up to ten years and at prices no less than fair market value for ISOs and no less than 85% of the fair market value for NSOs. Stock options granted generally vest over one to six years.

The following table summarizes the outstanding stock options under the 1999 Plan for the three months ended March 31, 2020:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances at December 31, 2019	191,706	\$ 93.40
Options cancelled	(12)	\$ 2,258.00
Balances at March 31, 2020	191,694	\$ 93.26

The Company chose the “straight-line” attribution method for allocating compensation costs of each stock option over the requisite service period using the Black-Scholes Option Pricing Model to calculate the grant date fair value.

The Company recorded compensation expense for these stock options grants of \$12,215 and \$30,564 for the three months ended March 31, 2020 and 2019, respectively.

As of March 31, 2020, there were unrecognized compensation costs of approximately \$26,488 related to non-vested stock option awards that will be recognized on a straight-line basis over the weighted average remaining vesting period of 0.61 years. Additionally, there were unrecognized compensation costs of approximately \$5.9 million related to non-vested stock option awards subject to performance-based vesting milestones. As of March 31, 2020, none of these milestones have been achieved, and are set to expire on April 3, 2020.

NOTE 8. SUBSEQUENT EVENTS

During the period April 2, 2020 through April 20, 2020, the Company received \$121 and issued 1,210,313 shares of common stock upon the exercise of its outstanding pre-funded warrants. As of April 20, 2020, there were no pre-funded warrants outstanding.

On April 30, 2020, the Company received a loan pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), as administered by the U.S. Small Business Administration (the “SBA”). The loan in the principal amount of \$244,657 (the “PPP Loan”) was disbursed by First Horizon Bank (the “Lender”) pursuant to a promissory note issued by the Company (the “Note”).

The Note has a two-year term and bears interest at a fixed rate of 1.00% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness, will commence on December 30, 2020. The Company did not provide any collateral or guarantees for the PPP Loan, nor did the Company pay any facility charge to obtain the PPP Loan. The Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations, and material adverse effects. The Company may prepay the principal of the PPP Loan at any time, subject to certain notice requirements.

Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and covered utilities during the eight-week period beginning on the approval date of the PPP Loan. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee in excess of \$100,000, prorated annually. Not more than 25% of the forgiven amount may be for non-payroll costs. Although the Company currently believes that its use of the PPP Loan will meet the conditions for forgiveness of the loan, the Company cannot assure that the PPP Loan will be forgiven, in whole or in part.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to them. In some cases you can identify forward-looking statements by words such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: the implications of interim or final results of our clinical trials, the progress of our research programs, including clinical testing, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our future operating expenses, our future losses, our future expenditures for research and development, our relationship with Orion, our ability to raise capital, the sufficiency of our cash resources, the impacts of the current COVID-19 pandemic and the eligibility for forgiveness of our loan, or the PPP Loan, received pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, as administered by the U.S. Small Business Administration, or the SBA. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q, Part I, Item 1A of our Annual Report on Form 10-K, and our other filings with the Securities and Exchange Commission, or SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from those we expect. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise.

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with the audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2019.

All references in this Quarterly Report to "Tenax Therapeutics", "we", "our" and "us" means Tenax Therapeutics, Inc.

Overview

Strategy

We are a specialty pharmaceutical company focused on identifying, developing and commercializing products that address cardiovascular and pulmonary diseases of high unmet medical need. Our principal business objective is to identify, develop and commercialize novel therapeutic products for disease indications that represent significant areas of clinical need and commercial opportunity. Our lead product is levosimendan, which was acquired in an asset purchase agreement with Phyxius Pharma, Inc., or Phyxius. Levosimendan is a calcium sensitizer developed for intravenous use in hospitalized patients with acutely decompensated heart failure. The treatment is currently approved in more than 60 countries for this indication.

The European Society of Cardiology, or the ESC, recommends levosimendan as a preferable agent over dobutamine to reverse the effect of beta blockade if it is thought to be contributing to hypotension. The ESC guidelines also state that levosimendan is not appropriate for patients with systolic blood pressure less than 85mmHg or in patients in cardiogenic shock unless it is used in combination with other inotropes or vasopressors. Other unique properties of levosimendan include sustained efficacy through the formation of a long acting metabolite, lack of impairment of diastolic function, and evidence of better compatibility with beta blockers than dobutamine.

We are currently conducting a Phase 2 clinical trial of levosimendan in North America for the treatment of patients with pulmonary hypertension associated with heart failure with preserved ejection fraction, or PH-HFpEF. PH-HFpEF is defined hemodynamically by a pulmonary artery pressure, or mPAP, ≥ 25 mmHg, a pulmonary capillary wedge pressure, or PCWP, >15 mmHg, and a diastolic pressure gradient, or diastolic PAP – PCWP, >7 mmHg. Pulmonary hypertension in these patients initially develops from a passive backward transmission of elevated filling pressures from left-sided heart failure. These mechanical components of pulmonary venous congestion may trigger pulmonary vasoconstriction, decreased nitric oxide availability, increased endothelin expression, desensitization to natriuretic peptide induced vasodilation, and vascular remodeling. Finally, these changes often lead to advanced pulmonary vascular disease, increased right ventricle, or RV, afterload, and RV failure.

PH-HFpEF is a common form of pulmonary hypertension with an estimated US prevalence exceeding 1.5 million patients. Currently, no pharmacologic therapies are approved for treatment of PH-HFpEF. Despite the fact that many therapies have been studied in PH-HFpEF patients, including therapies approved to treat pulmonary arterial hypertension patients, no therapies have been shown to be effective in treating PH-HFpEF patients.

Published pre-clinical and clinical studies indicate that levosimendan may provide important benefits to patients with pulmonary hypertension. Data from these published trials indicate that levosimendan may reduce pulmonary vascular resistance and improve important cardiovascular hemodynamics such as reduced pulmonary capillary wedge pressure in patients with pulmonary hypertension. In addition, several published studies provide evidence that levosimendan may improve right ventricular dysfunction which is a common comorbidity in patients with pulmonary hypertension. While none of these studies have focused specifically on PH-HFpEF patients, the general hemodynamic improvements in these published studies of various types of pulmonary hypertension provide an indication that levosimendan may be beneficial in PH-HFpEF patients.

In March 2018, we met with the United States Food and Drug Administration, or FDA, to discuss development of levosimendan in PH-HFpEF patients. The FDA agreed with our planned Phase 2 design, patient entry criteria, and endpoints. It was agreed the study could be conducted under the existing investigational new drug application with no additional nonclinical studies required to support full development. The FDA recognized there were no approved drug therapies to treat PH-HFpEF patients and acknowledged this provided an opportunity for a limited Phase 3 clinical program. This topic will be discussed further at the End-of-Phase 2 Meeting following completion of the Phase 2 study in PH-HFpEF patients, which is known as the HELP Study – Hemodynamic Evaluation of Levosimendan in PH-HFpEF. We initiated the first of our expected 10-12 HELP Study clinical sites in November 2018 and the first of 36 patients was enrolled in the HELP Study in March 2019. Enrollment in the HELP Study was completed in March 2020. The primary endpoint of the HELP Study is based on change in PCWP vs baseline compared to placebo. The HELP Study utilizes a double-blind randomized design following five weekly infusions of levosimendan. The primary endpoint data will be available once the HELP Study data is unblinded.

The HELP Study design is novel in several respects. To date, no other multi-center levosimendan study has evaluated levosimendan in heart failure patients with preserved ejection fraction (HFpEF) or PH-HFpEF patients. Instead, all previous levosimendan heart failure studies have enrolled heart failure patients with reduced ejection fraction (HFrEF), which specifically excluded HFpEF patients. Also, the HELP Study utilizes a unique 24-hour weekly infusion regimen of 0.075- 0.1µm/kg/min. Finally, the HELP Study employs a unique home-based IV infusion administration via an ambulatory infusion pump. This home-based weekly IV administration is unlike all other chronic dosing studies of levosimendan that have typically employed a shorter duration and less frequent infusion regimen administered in a hospital setting. Despite the unique patient population, weekly dosing, and home-based administration, there have been no reported serious adverse events reported.

Investigator reported open-label data from the HELP Study has provided encouraging preliminary signs of efficacy during the initial lead-in infusion phase of the trial. The open-label lead-in infusion phase is designed to identify responders prior to randomization. Approximately 84% of patients met the lead infusion responder criteria. Analysis of investigator reported data following the 24-hour open-label levosimendan lead-in infusion for the 37 evaluable responders indicated the following mean changes in exercise hemodynamics: PCWP of -7.5mm Hg, exercise right atrial pressure of -5.0mm Hg, mean pulmonary arterial pressure (mPAP) of -5.1 mm Hg and an increase in cardiac output of 0.6 liter/min.

First Quarter 2020 Highlights

The following summarizes certain key financial measures for the three months ended March 31, 2020:

- Cash and cash equivalents, including the fair-value of our marketable securities, were \$4.9 million on March 31, 2020.
- Our net loss from operations was \$2.7 million for the first quarter of fiscal 2020 compared to \$1.7 million for the three months ended March 31, 2019.
- Net cash used in operating activities was \$2.7 million and \$2.1 million for the three months ended March 31, 2020 and 2019, respectively.

Opportunities and Trends

The continued spread of COVID-19 globally could adversely affect our ability to retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some of these investigators and site staff may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede movement or interrupt healthcare services, or if they become infected with COVID-19 themselves, which would delay our ability to complete our Phase 2 HELP Study or release clinical trial results.

As we focus on the development of our existing product candidate, we also continue to position ourselves to execute upon licensing and other partnering opportunities. To do so, we will need to continue to maintain our strategic direction, manage and deploy our available cash efficiently and strengthen our collaborative research development and partner relationships.

During 2020, we are focused on the following initiatives:

- Working with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercialization capabilities; and
- Identifying strategic alternatives, including, but not limited to, the potential acquisition of additional products or product candidates.

Financial Overview

Results of Operations- Comparison of the Three Months Ended March 31, 2020 and 2019

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for executive, finance, legal and administrative personnel, including stock-based compensation. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, legal and accounting services, other professional services, and consulting fees. General and administrative expenses and percentage changes for the three months ended March 31, 2020 and 2019, respectively, are as follows:

	For the year ended March 31,			
	2020	2019	Increase/ (Decrease)	% Increase/ (Decrease)
Personnel costs	\$ 737,269	\$ 713,482	\$ 23,787	3%
Legal and professional fees	357,831	321,282	36,549	11%
Other costs	189,593	107,458	82,135	76%
Facilities	38,266	36,787	1,479	4%

Personnel costs:

Personnel costs remained relatively consistent for the three months ended March 31, 2020 and 2019.

Legal and professional fees:

Legal and professional fees consist of the costs incurred for legal fees, accounting fees, capital market expenses, consulting fees and investor relations services, as well as fees paid to our Board of Directors. Legal and professional fees increased approximately \$37,000 for the three months ended March 31, 2020 compared to the same period in the prior year. This increase was due primarily to increases in costs incurred for legal fees and investor relations services, partially offset by overall decreases in accounting and consulting fees.

- Legal fees increased approximately \$29,000 in the current period. This increase was due primarily to costs incurred for arbitration partially offset by a reduction in fees associated with securities filings and other matters in the current period as compared to the same period in the prior year.
- Investor relations costs increased approximately \$19,000 in the current period. This increase was primarily due to fees paid to a third-party investor relations firm in the current period that were not incurred in the same period in the prior year.

Other costs:

Other costs include costs incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. Other costs increased approximately \$82,000 for the three months ended March 31, 2020 compared to the same period in the prior year. This increase was due primarily to an increase in the cost of annual insurance premiums and the payment of state franchise taxes in the current period.

Facilities:

Facilities expenses include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs remained relatively consistent for the three months ended March 31, 2020 and 2019.

Research and Development Expenses

Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of manufacturing and supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, laboratory and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the three months ended March 31, 2020 and 2019, respectively, are as follows:

	For the year ended March 31,			
	2020	2019	Increase/ (Decrease)	% Increase/ (Decrease)
Clinical and preclinical development	\$ 1,282,662	\$ 419,597	\$ 863,065	206%
Personnel costs	55,143	58,585	(3,442)	(6)%
Other costs	4,721	4,585	136	3%

Clinical and preclinical development:

Clinical and preclinical development costs include, primarily, the costs associated with our Phase 2 HELP Study for levosimendan, which was initiated during fiscal year 2018. The increase of approximately \$863,000 in clinical and preclinical development costs for the three months ended March 31, 2020 compared to the same period in the prior year was primarily due to an increase of approximately \$470,000 in expenditures for CRO costs and clinical research associates to manage the Phase 2 HELP Study, as well as an increase of approximately \$480,000 in enrolled patient costs, partially offset by a reduction of approximately \$68,000 in other direct costs associated with clinical site activations and approximately \$19,000 in nonclinical development costs for levosimendan subcutaneous formulation as compared to the same period in the prior year.

Personnel costs:

Personnel costs remained relatively consistent for the three months ended March 31, 2020 and 2019.

Other costs:

Other costs remained relatively consistent for the three months ended March 31, 2020 and 2019.

The process of conducting preclinical studies and clinical trials necessary to obtain approval from the FDA is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among other things, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, uncertainty associated with clinical trial enrollment and risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are currently focused on developing our most advanced product candidate, levosimendan; however, we will need substantial additional capital in the future in order to complete the development and potential commercialization of levosimendan, and to continue with the development of other potential product candidates.

Other income and expense, net

Other income and expense include non-operating income and expense items not otherwise recorded in our condensed consolidated statement of comprehensive loss. These items include, but are not limited to, changes in the fair value of financial assets and derivative liabilities, interest income earned and fixed asset disposals. Other income for the three months ended March 31, 2020 and 2019, respectively, is as follows:

	<u>For the year ended March 31,</u>		<u>(Increase)/ Decrease</u>
	<u>2020</u>	<u>2019</u>	
Other income, net	\$ (10,841)	\$ (44,331)	\$ 33,490

Other income decreased approximately \$33,000 for the three months ended March 31, 2020 compared to the same period in the prior year. This decrease is due primarily to a decrease in the interest earned on our investment in marketable securities.

During the three months ended March 31, 2020, we recorded interest income of approximately \$10,000 from our investments in marketable securities. This income is derived from approximately \$10,000 in bond interest paid partially offset by fair-value adjustments measured for the period, which compares to approximately \$42,000 in bond interest paid during the same period in the prior year.

Liquidity, Capital Resources and Plan of Operation

We have incurred losses since our inception, and as of March 31, 2020 we had an accumulated deficit of approximately \$239 million. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we will continue to incur net losses for at least the next several years. We expect to incur increased expenses related to our development and potential commercialization of levosimendan for pulmonary hypertension and other potential indications, as well as identifying and developing other potential product candidates and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

Liquidity

We have financed our operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. We had total current assets of \$5,798,358 and \$6,180,829 and working capital of \$3,292,907 and \$3,648,434 as of March 31, 2020 and December 31, 2019, respectively. Based on our working capital and the value of our investments in marketable securities on March 31, 2020, we believe we have sufficient capital to fund our operations through the third quarter of calendar year 2020.

Cash Flows

The following table shows a summary of our cash flows for the three months ended March 31, 2020 and 2019:

	Three months ended March 31,	
	2020	2019
Net cash used in operating activities	\$ (2,671,029)	\$ (2,132,811)
Net cash used in investing activities	(6,330)	(8,805)
Net cash provided by financing activities	2,130,045	96,500

Net cash used in operating activities. Net cash used in operating activities was approximately \$2.7 million for the three months ended March 31, 2020 compared to net cash used in operating activities of approximately \$2.1 million for the three months ended March 31, 2019. The increase in cash used for operating activities was due primarily to an increase in our costs related to the Phase 2 Help Study in the current period.

Net cash used in investing activities. Net cash used in investing activities was approximately \$6,000 for the three months ended March 31, 2020 compared to approximately \$9,000 used in the three months ended March 31, 2019. The decrease in cash used in investing activities was primarily due to a decrease in the purchase of marketable securities in the current period.

Net cash provided by financing activities. Net cash provided by financing activities was approximately \$2.1 million for the three months ended March 31, 2020 compared to \$97,000 for the three months ended March 31, 2019. The increase in cash provided by financing activities was due to the issuance of common stock in the current period.

Recent Development

On April 30, 2020, we received a loan pursuant to the Paycheck Protection Program under the CARES Act, as administered by the SBA. The PPP loan in the principal amount of \$244,657 was disbursed by First Horizon Bank, or the Lender, pursuant to a promissory note issued by us, or the Note.

The Note has a two-year term and bears interest at a fixed rate of 1.00% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (discussed below), will commence on December 30, 2020. We did not provide any collateral or guarantees for the PPP Loan, nor did we pay any facility charge to obtain the PPP Loan. The Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations, and material adverse effects. We may prepay the principal of the PPP Loan at any time, subject to certain notice requirements.

Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and covered utilities during the eight-week period beginning on the approval date of the PPP Loan. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee in excess of \$100,000, prorated annually. Not more than 25% of the forgiven amount may be for non-payroll costs. Although we currently believe that our use of the PPP Loan will meet the conditions for forgiveness of the loan, we cannot assure that the PPP Loan will be forgiven, in whole or in part.

Operating Capital and Capital Expenditure Requirements

Our future capital requirements will depend on many factors that include, but are not limited to the following:

- the initiation, progress, timing and completion of clinical trials for our product candidate and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- delays that may be caused by the global coronavirus pandemic. The continued spread of COVID-19 globally could adversely affect our ability to retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some of these investigators and site staff may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede movement or interrupt healthcare services, or if they become infected with COVID-19 themselves, which would delay our ability to complete our Phase 2 HELP Study or release clinical trial results;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future collaboration, licensing, consulting or other arrangements that we may enter into;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the possible costs of litigation.

We believe that our existing cash and cash equivalents, along with our investment in marketable securities, will be sufficient to fund our projected operating requirements through the third quarter of calendar year 2020. We will need substantial additional capital in the future in order to complete the development and commercialization of levosimendan and to fund the development and commercialization of other future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. For information regarding our critical accounting policies and estimates, please refer to “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Summary of Significant Accounting Policies” contained in our Annual Report on Form 10-K for the year ended December 31, 2019. During the three months ended March 31, 2020, there were no material changes to the critical accounting policies previously disclosed in that report.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board, or FASB, issued an accounting standard intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740, Income Taxes and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. We are currently evaluating this standard, but we do not believe the adoption of the new guidance will have a material impact on our consolidated financial statements.

In June 2016, the FASB issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard requires that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2023, with early adoption permitted. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. We do not believe the adoption of this standard will have a material impact on our consolidated financial statements and related disclosures.

Contractual Obligations

There have been no material changes, outside of the ordinary course of business, to our contractual obligations as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by paragraph (b) of Rules 13a-15 and 15d-15 promulgated under the Exchange Act, our management, including our Interim Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e) and 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2020, the end of the period covered by this report in that they provide reasonable assurance that the information we are required to disclose in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods required by the SEC and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no significant changes in our internal control over financial reporting during our most recently completed fiscal quarter that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We routinely review our internal controls over financial reporting and from time to time make changes intended to enhance the effectiveness of our internal control over financial reporting. We will continue to evaluate the effectiveness of our disclosure controls and procedures and internal controls over financial reporting on an ongoing basis and will take action as appropriate.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

There are no material pending legal proceedings to which we are a party or to which any of our property is subject.

ITEM 1A. RISK FACTORS

The risks we face have not materially changed from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, except as set forth below:

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely affect our business and our financial results.

The spread of COVID-19 has affected segments of the global economy and may affect our operations, including the potential interruption of our clinical trial activities and our supply chain. The continued spread of COVID-19 may result in a period of business disruption, including delays in our clinical trials or delays or disruptions in our supply chain. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

The continued spread of COVID-19 globally could adversely affect our clinical trial operations in the United States and elsewhere, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with COVID-19 themselves, which would delay our ability to conduct clinical trials or release clinical trial results. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials, which could result in inefficiencies due to reductions in staff and disruptions to work environments.

The spread of COVID-19, or another infectious disease, could also negatively affect the operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. In addition, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

Our PPP Loan may not be forgiven or may subject us to challenges and investigations regarding qualification for the loan.

On April 30, 2020, we received the PPP Loan in the principal amount of \$244,657 pursuant to the Paycheck Protection Program under the CARES Act, as administered by the SBA. The PPP Loan matures in April 2022 and has an annual interest rate of 1.00%. Payments of principal and interest are deferred until December 2020. Pursuant to Section 1106 of the CARES Act, we may apply for and be granted forgiveness for all or a portion of the PPP Loan. Such forgiveness will be determined, subject to limitations, based on the use of the loan proceeds for qualifying expenses, which include payroll costs, rent, and utility costs over the eight-week measurement period following receipt of the loan proceeds.

The SBA continues to develop and issue new and updated guidance regarding the Paycheck Protection Program loan application process, including guidance regarding required borrower certifications and requirements for forgiveness of loans made under the program. We continue to track the guidance as it is released and assess and re-assess various aspects of its application as necessary based on the guidance. However, in the absence of final guidance or regulations and based on our projected ability to use the loan proceeds for qualifying expenses, we cannot give any assurance that the PPP Loan will be forgiven in whole or in part.

Additionally, the PPP Loan application required us to certify that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP Loan, we are found to have been ineligible to receive the PPP Loan or in violation of any of the laws or regulations that apply to us in connection with the PPP Loan, including the False Claims Act, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan. In the event that we seek forgiveness of all or a portion of the PPP Loan, we will also be required to make certain certifications which will be subject to audit and review by governmental entities and could subject us to significant penalties and liabilities if found to be inaccurate. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could harm our business, results of operations and financial condition.

Our failure to maintain compliance with Nasdaq’s continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On April 24, 2020, we received a notification letter from Nasdaq’s Listing Qualifications Department indicating that we are not in compliance with Nasdaq Listing Rule 5550(a)(2), because the minimum bid price of our common stock on the Nasdaq Capital Market has closed below \$1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days to regain compliance with the minimum bid requirement; however, due to the market disruption caused by the ongoing COVID-19 pandemic, Nasdaq has tolled the requirement for meeting the minimum bid price until June 30, 2020. As such, we have 180 days from July 1, 2020, or until December 28, 2020, to achieve compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for at least ten consecutive business days before December 28, 2020. If we do not regain compliance during this cure period, we expect that Nasdaq will provide written notification to us that our common stock will be delisted. At that time, we may appeal Nasdaq’s delisting determination to a Nasdaq hearing panel.

While we intend to engage in efforts to regain compliance, and thus maintain our listing, there can be no assurance that we will be able to regain compliance during the applicable time periods set forth above. If we fail to continue to meet all applicable Nasdaq Capital Market requirements in the future and Nasdaq determines to delist our common stock, the delisting could substantially decrease trading in our common stock; adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws; adversely affect our ability to obtain financing on acceptable terms, if at all; and may result in the potential loss of confidence by investors, suppliers, customers, and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further and shareholders may lose some or all of their investment.

ITEM 6. EXHIBITS

The following exhibits are being filed herewith and are numbered in accordance with Item 601 of Regulation S-K:

No.	Description
10.1	Note, dated April 30, 2020, between Tenax Therapeutics, Inc. and First Horizon Bank.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TENAX THERAPEUTICS, INC.

Date: May 15, 2020

By: /s/ Michael B. Jebsen

Michael B. Jebsen
President and Chief Financial Officer
(On behalf of the Registrant and as Principal
Financial Officer)



U.S. Small Business Administration

NOTE

SBA Loan #	65865872-04
SBA Loan Name	Tenax Therapeutics, Inc.
Date	04/30/2020
Loan Amount	\$ 244,657.00
Interest Rate	1.00%
Borrower	Tenax Therapeutics, Inc.
Operating Company	Tenax Therapeutics, Inc.
Lender	First Horizon Bank

1. PROMISE TO PAY:

In return for the Loan, Borrower promises to pay to the order of Lender the amount of two hundred forty-four thousand six hundred fifty-seven interest on the unpaid principal balance, and all other amounts required by this Note.

1. DEFINITIONS:

"Collateral" means any property taken as security for payment of this Note or any guarantee of this Note. "Guarantor" means each person or entity that signs a guarantee of payment of this Note.

"Loan" means the loan evidenced by this Note.

"Loan Documents" means the documents related to this loan signed by Borrower, any Guarantor, or anyone who pledges collateral.

"SBA" means the Small Business Administration, an Agency of the United States of America.

3. PAYMENT TERMS:

Borrower must make all payments at the place Lender designates. The payment terms for this Note are:

Maturity: This Note will mature in 2 years and 0 months from date of Note.

Repayment terms:

The interest rate is 1% per year. The interest rate may only be changed in accordance with SOP 50 10.

Borrower must pay principal and interest payments of \$ 13,767.62 every month, beginning seven months from the month this Note is dated; payments must be made on the 30th calendar day in the months they are due.

Lender will apply each installment first to pay interest accrued to the day Lender receives the payment, then to bring principal current, then to pay any late fees, and will apply any remaining balance to reduce principal.

Loan Prepayment:

Notwithstanding any provision in this Note to the contrary:

Borrower may prepay this Note. Borrower may prepay 20 percent or less of the unpaid principal balance at any time without notice. If Borrower prepays more than 20 percent and the Loan has been sold on the secondary market, Borrower must:

- a. Give Lender written notice;
- b. Pay all accrued interest; and
- c. If this prepayment is received less than 21 days from the date Lender receives the notice, pay an amount equal to 21 days' interest from the date lender receives the notice, less any interest accrued during the 21 days and paid under subparagraph b., above.

If Borrower does not prepay within 30 days from the date Lender receives the notice, Borrower must give Lender a new notice.

All remaining principal and accrued interest is due and payable 2 years and 0 months from date of Note.

Late Charge: If payment on this Note is more than 10 days late, Lender may charge Borrower a late fee of up to 5.00 of the unpaid portion of the regularly scheduled payment.

4. DEFAULT:

Borrower is in default under this Note if Borrower does not make a payment when due under this Note, or if Borrower or Operating Company:

- A. Fails to do anything required by this Note and other Loan Documents;
- B. Defaults on any other loan with Lender;
- C. Does not preserve, or account to Lender's satisfaction for, any of the Collateral or its proceeds;
- D. Does not disclose, or anyone acting on their behalf does not disclose, any material fact to Lender or SBA;
- E. Makes, or anyone acting on their behalf makes, a materially false or misleading representation to Lender or SBA;
- F. Defaults on any loan or agreement with another creditor, if Lender believes the default may materially affect Borrower's ability to pay this Note;
- G. Fails to pay any taxes when due;
- H. Becomes the subject of a proceeding under any bankruptcy or insolvency law;
- I. Has a receiver or liquidator appointed for any part of their business or property;
- J. Makes an assignment for the benefit of creditors;
- K. Has any adverse change in financial condition or business operation that Lender believes may materially affect Borrower's ability to pay this Note;
- L. Reorganizes, merges, consolidates, or otherwise changes ownership or business structure without Lender's prior written consent; or
- M. Becomes the subject of a civil or criminal action that Lender believes may materially affect Borrower's ability to pay this Note.

5. LENDER'S RIGHTS IF THERE IS A DEFAULT:

Without notice or demand and without giving up any of its rights, Lender may:

- A. Require immediate payment of all amounts owing under this Note;
- B. Collect all amounts owing from any Borrower or Guarantor;
- C. File suit and obtain judgment;
- D. Take possession of any Collateral; or
- E. Sell, lease, or otherwise dispose of, any Collateral at public or private sale, with or without advertisement.

6. LENDER'S GENERAL POWERS:

Without notice and without Borrower's consent, Lender may:

- A. Bid on or buy the Collateral at its sale or the sale of another lienholder, at any price it chooses;
- B. Incur expenses to collect amounts due under this Note, enforce the terms of this Note or any other Loan Document, and preserve or dispose of the Collateral. Among other things, the expenses may include payments for property taxes, prior liens, insurance, appraisals, environmental remediation costs, and reasonable attorney's fees and costs. If Lender incurs such expenses, it may demand immediate repayment from Borrower or add the expenses to the principal balance;
- C. Release anyone obligated to pay this Note;
- D. Compromise, release, renew, extend or substitute any of the Collateral; and
- E. Take any action necessary to protect the Collateral or collect amounts owing on this Note.

7. WHEN FEDERAL LAW APPLIES:

When SBA is the holder, this Note will be interpreted and enforced under federal law, including SBA regulations. Lender or SBA may use state or local procedures for filing papers, recording documents, giving notice, foreclosing liens, and other purposes. By using such procedures, SBA does not waive any federal immunity from state or local control, penalty, tax, or liability. As to this Note, Borrower may not claim or assert against SBA any local or state law to deny any obligation, defeat any claim of SBA, or preempt federal law.

8. SUCCESSORS AND ASSIGNS:

Under this Note, Borrower and Operating Company include the successors of each, and Lender includes its successors and assigns.

9. GENERAL PROVISIONS:

- A. All individuals and entities signing this Note are jointly and severally liable.
- B. Borrower waives all suretyship defenses.
- C. Borrower must sign all documents necessary at any time to comply with the Loan Documents and to enable Lender to acquire, perfect, or maintain Lender's liens on Collateral.
- D. Lender may exercise any of its rights separately or together, as many times and in any order it chooses. Lender may delay or forgo enforcing any of its rights without giving up any of them.
- E. Borrower may not use an oral statement of Lender or SBA to contradict or alter the written terms of this Note.
- F. If any part of this Note is unenforceable, all other parts remain in effect.
- G. To the extent allowed by law, Borrower waives all demands and notices in connection with this Note, including presentment, demand, protest, and notice of dishonor. Borrower also waives any defenses based upon any claim that Lender did not obtain any guarantee; did not obtain, perfect, or maintain a lien upon Collateral; impaired Collateral; or did not obtain the fair market value of Collateral at a sale.

10. STATE-SPECIFIC PROVISIONS:

The following provision applies when a borrower is a resident of WISCONSIN:

Each Borrower who is married represents that this obligation is incurred in the interest of his or her marriage or family.

The following Confession of Judgment provision applies when a borrower is a resident of DELAWARE: WARRANT OF ATTORNEY/CONFESSION OF JUDGMENT. In addition to any other remedies Lender may possess, Borrower knowingly, voluntarily and intentionally authorizes any attorney to appear on behalf of Borrower, from time to time, in any court of record possessing jurisdiction over this Note and to waive issuance and service of process and to confess judgment in favor of Lender against Borrower, for the unpaid principal, accrued interest, accrued charges, reasonable attorney fees and court costs and such other amount due under this Note.

The following Confession of Judgment provision applies when a borrower is a resident of MARYLAND: WARRANT OF ATTORNEY/CONFESSION OF JUDGMENT. Borrower authorizes an attorney to appear in a court of record and confess judgment, without process, against Borrower in favor of Lender for all indebtedness owed in connection with the loan, including but not limited to service charges, other charges and reasonable attorney's fees.

The following Confession of Judgment provision applies when a borrower is a resident of OHIO:

WARRANT OF ATTORNEY/CONFESSION OF JUDGMENT. In addition to any other remedies Lender may possess, Borrower knowingly, voluntarily and intentionally authorizes any attorney to appear on behalf of Borrower, from time to time, in any court of record possessing jurisdiction over this Note and to waive issuance and service of process and to confess judgment in favor of Lender against Borrower, for the unpaid principal, accrued interest, accrued charges, reasonable attorney fees and court costs and such other amount due under this Note.

WARNING: BY SIGNING THIS PAPER YOU GIVE UP YOUR RIGHT TO NOTICE AND COURT TRIAL. IF YOU DO NOT PAY ON TIME, A COURT JUDGMENT MAY BE TAKEN AGAINST YOU WITHOUT YOUR PRIOR KNOWLEDGE AND THE POWERS OF THE COURT CAN BE USED TO COLLECT FROM YOU REGARDLESS OF ANY CLAIMS YOU MAY HAVE AGAINST THE CREDITOR WHETHER FOR RETURNED GOODS, FAULTY GOODS, FAILURE ON HIS PART TO COMPLY WITH THE AGREEMENT OR ANY OTHER CAUSE.

The following Confession of Judgment provision applies when a borrower is a resident of PENNSYLVANIA: WARRANT OF ATTORNEY/CONFESSION OF JUDGMENT. Borrower irrevocably authorizes and empowers the prothonotary, any attorney or any clerk of any court of record, upon default, to appear for and confess judgment against Borrower for such sums as are due and/or may become due under this Note including costs of suit, without stay of execution, and for attorney's fees and costs as set forth in this Note and knowingly, voluntarily and intentionally waives any and all rights Borrower may have to notice and hearing under the state and federal laws prior to entry of a judgment. To the extent permitted by law, Borrower releases all errors in such proceedings. If a copy of this Note, verified by or on behalf of the holder shall have been filed in such action, it shall not be necessary to file the original Note as a warrant of attorney. The authority and power to appear for and confess judgment against Borrower shall not be exhausted by the initial exercise thereof and may be exercised as often as the holder shall find it necessary and desirable and this Note shall be a sufficient warrant for such authority and power.

The following Confession of Judgment provision applies when a borrower is a resident of VIRGINIA: IMPORTANT NOTICE: THIS INSTRUMENT CONTAINS A CONFESSION OF JUDGMENT PROVISION WHICH CONSTITUTES A WAIVER OF IMPORTANT RIGHTS YOU MAY HAVE AS A DEBTOR AND ALLOWS THE CREDITOR TO OBTAIN A JUDGMENT AGAINST YOU WITHOUT ANY FURTHER NOTICE.

WARRANT OF ATTORNEY/CONFESSION OF JUDGMENT. In addition to any other remedies Lender may possess, Borrower knowingly, voluntarily and intentionally authorizes to appear on behalf of Borrower, from time to time, in the District Court of Alexandria, Virginia and to waive issuance and service of process and to confess judgment in favor of Lender against Borrower, for the unpaid principal, accrued interest, accrued charges, reasonable attorney fees and court costs and such other amount due under this Note.

The following Oral Agreements Disclaimer provision applies when the borrower is a resident of MISSOURI: Oral or unexecuted agreements or commitments to loan money, extend credit or to forbear from enforcing repayment of a debt including promises to extend or renew such debt are not enforceable, regardless of the legal them upon which it is based that is in any way related to the credit agreement. To protect you (Borrowers(s)) and us (Creditor) from misunderstanding or disappointment, any agreements we reach covering such matters are contained in this writing, which is the complete and exclusive statement of the agreement between us, except as we may later agree in writing to modify

10. STATE-SPECIFIC PROVISIONS (CONTINUED):

The following Oral Agreements Disclaimer provision applies when the borrower is a resident of OREGON: UNDER OREGON LAW, MOST AGREEMENTS, PROMISES AND COMMITMENTS MADE BY [BENEFICIARY]/ US CONCERNING LOANS AND OTHER CREDIT EXTENSIONS WHICH ARE NOT FOR PERSONAL, FAMILY, OR HOUSEHOLD PURPOSES OR SECURED SOLELY BY GRANTOR'S/ BORROWER'S RESIDENCE MUST BE IN WRITING, EXPRESS CONSIDERATION AND BE SIGNED BY [AN AUTHORIZED REPRESENTATIVE OF BENEFICIARY]/US TO BE ENFORCEABLE.

The following Oral Agreements Disclaimer provision applies when the borrower is a resident of WASHINGTON: Oral agreements or oral commitments to loan money, extend credit, or to forbear from enforcing repayment of a debt are not enforceable under Washington law.

The following provision applies when the borrower is a resident of ALASKA:

The Mortgagor or Trustor (Borrower) is personally obligated and fully liable for the amount due under the Note. The Mortgagee or Beneficiary (Lender) has the right to sue on the Note and obtain a personal judgment against the Mortgagor or Trustor for the satisfaction of the amount due under the Note either before or after a judicial foreclosure of the Mortgage or Deed of Trust as under AS 09.45.170-09.45.220.

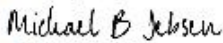
The following Oral Agreements Disclaimer provision applies when the borrower is a resident of IOWA: IMPORTANT: READ BEFORE SIGNING. The terms of this agreement should be read carefully because only those terms in writing are enforceable. No other terms or oral promises not contained in this written contract may be legally enforced. You may change the terms of this agreement only by another written agreement.

The following Oral Agreements Disclaimer provision applies when the borrower is a resident of UTAH:

This is a final expression of the agreement between the creditor and debtor and the written agreement may not be contradicted by evidence of any alleged oral agreement.

11. BORROWER'S NAME(S) AND SIGNATURE(S):

By signing below, each individual or entity becomes obligated under this Note as Borrower.

Tenax Therapeutics, Inc.	
<small>DocuSigned by:</small>	
	
<small>74D23DF37F73418</small>	
_____ Signature of Authorized Representative of Borrower/Borrower	_____ 04/30/2020 Date
_____ Michael B. Jebsen Name of Authorized Representative of Borrower	_____ Chief Financial Officer Title

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Anthony DiTonno, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tenax Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2020

/s/ Anthony DiTonno

Anthony DiTonno
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael B. Jebsen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tenax Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2020

/s/ Michael B. Jebsen

Michael B. Jebsen

*President and Chief Financial Officer
(Principal Financial Officer)*

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anthony DiTonno, Chief Executive Officer (Principal Executive Officer) of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2020

/s/ Anthony DiTonno

Anthony DiTonno

Chief Executive Officer

(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION OF INTERIM CHIEF EXECUTIVE OFFICER AND
CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael B. Jebsen, President and Chief Financial Officer (Principal Financial Officer) of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2020

/s/ Michael B. Jebsen

Michael B. Jebsen

President and Chief Financial Officer

(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
